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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,144	06/15/2001	Preben Nielsen	10033.200-US	7990

25908 7590 10/03/2003

NOVOZYMES NORTH AMERICA, INC.  
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NEW YORK, NY 10110

EXAMINER

BYRD, DEVON R

ART UNIT PAPER NUMBER

1639

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/882,144

Applicant(s)

NIELSEN ET AL.

Examiner

Devon R Byrd

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FILE  
COPY

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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DETAILED ACTION

*ELECTION/RESTRICTIONS*

RESTRICTION TO ONE OF THE FOLLOWING INVENTIONS IS REQUIRED UNDER 35 U.S.C.

121:

- I. CLAIMS 1-7, DRAWN TO A METHOD FOR SCREENING FOR COMPOUNDS SECRETED BY AN ORGANISM, CLASSIFIED IN CLASS 435, SUBCLASS 4.
- II. CLAIMS 1, 8 AND 9, DRAWN TO A METHOD FOR IDENTIFYING CLONES THAT PRODUCE A COMPOUND EXHIBITING [A] DESIRED FUNCTIONALITY, CLASSIFIED IN CLASS 436, SUBCLASS 63.
- III. CLAIMS 1, 10, AND 11, DRAWN TO A METHOD FOR SCREENING AN EXOGENOUS GENE LIBRARY, CLASSIFIED IN CLASS 435, SUBCLASS 41.
- IV. CLAIMS 12-14, DRAWN TO A COMPOUND OBTAINED BY THE PROCESS OF CLAIM 1, WHICH IS UNCLASSIFIABLE IN ITS BROADEST READING.
- V. CLAIM 15, DRAWN TO A METHOD FOR IDENTIFYING A NUCLEOTIDE SEQUENCE, CLASSIFIED IN CLASS 702, SUBCLASS 20.
- VI. CLAIM 16, DRAWN TO A NUCLEOTIDE SEQUENCE OBTAINED BY THE PROCESS OF CLAIM 15, WHICH IS UNCLASSIFIABLE IN ITS BROADEST READING.
- VII. CLAIMS 17 AND 18, DRAWN TO A METHOD FOR SCREENING MICROORGANISMS THAT SECRETE A COMPOUND, CLASSIFIED IN CLASS 702, SUBCLASS 19.
- VIII. CLAIMS 17 AND 19, DRAWN TO A METHOD FOR SCREENING MICROORGANISMS THAT SECRETE A COMPOUND, CLASSIFIED IN CLASS 702, SUBCLASS 19.
- IX. CLAIM 20, DRAWN TO A MICROORGANISM OBTAINED BY THE PROCESS OF CLAIM 17, WHICH IS UNCLASSIFIABLE IN ITS BROADEST READING.

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NOTE: CLAIMS 1 AND 17 ARE LISTED IN MULTIPLE GROUPS SINCE THEY WERE FOUND TO BE "GENERIC" TO SAID GROUPS. UPON ELECTION OF A SINGLE GROUP, SAID CLAIMS WILL BE EXAMINED ACCORDING TO THE LIMITATIONS OF THE ELECTED GROUP.

RESTRICTION IS DEEMED PROPER BECAUSE CERTAIN OF THE ABOVE METHODS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS I-III, V, VII, AND VIII ARE DIRECTED TO METHODS THAT RECITE STRUCTURALLY AND FUNCTIONALLY DISTINCT ELEMENTS, ARE NOT REQUIRED FOR ONE ANOTHER, AND ACHIEVE DIFFERENT GOALS.

RESTRICTION IS DEEMED PROPER BECAUSE CERTAIN OF THE ABOVE INVENTIVE GROUPS ARE DIRECTED TO DIFFERENT PRODUCTS. RESTRICTION IS DEEMED PROPER BECAUSE THESE PRODUCTS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS IV, VI, AND IX ARE DIRECTED TO PRODUCTS THAT ARE DISTINCT BOTH PHYSICALLY AND FUNCTIONALLY, ARE NOT REQUIRED FOR ONE ANOTHER, AND ARE THEREFORE PATENTABLY DISTINCT.

INVENTIONS I-III, V, VII, AND VIII ARE RELATED TO INVENTIONS IV, V, AND IX AS PROCESS OF MAKING AND PRODUCT MADE. THE INVENTIONS ARE DISTINCT IF EITHER OR BOTH OF THE FOLLOWING CAN BE SHOWN: (1) THAT THE PROCESS AS CLAIMED CAN BE USED TO MAKE OTHER AND MATERIALLY DIFFERENT PRODUCT OR (2) THAT THE PRODUCT AS CLAIMED CAN BE MADE BY ANOTHER AND MATERIALLY DIFFERENT PROCESS (MPEP § 806.05(F)). IN THE INSTANT CASE THE PRODUCT OF GROUP IV COULD BE MADE BY A MATERIALLY DIFFERENT PROCESS, SUCH AS BY CHROMATOGRAPHIC PARTITIONING. THE PRODUCT OF GROUP V COULD BE MADE BY A MATERIALLY DIFFERENT PROCESS, SUCH AS BY REVERSE GENETICS. THE PRODUCT OF GROUP IX COULD BE MADE BY A MATERIALLY DIFFERENT PROCESS, SUCH AS BY ISOLATION BASED UPON BIOCHEMICAL PHENOTYPING.

BECAUSE THESE INVENTIONS ARE DISTINCT FOR THE REASONS GIVEN ABOVE, AND

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- A. HAVE ACQUIRED A SEPARATE STATUS IN THE ART AS SHOWN BY THEIR DIFFERENT CLASSIFICATION;
- B. HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND,
- C. HAVE DIVERGENT SUBJECT MATTER, RESTRICTION FOR EXAMINATION PURPOSES AS INDICATED IS PROPER.

APPLICANT IS ADVISED THAT THE REPLY TO THIS REQUIREMENT TO BE COMPLETE MUST INCLUDE AN ELECTION OF THE INVENTION TO BE EXAMINED EVEN THOUGH THE REQUIREMENT BE TRAVERSED (37 CFR 1.143).

*ELECTION OF SPECIES (ALL GROUPS)*

CLAIMS 1, 15, AND 17 ARE UNSEARCHABLE, AS THEY ARE "GENERIC" TO A PLURALITY OF DISCLOSED PATENTABLY DISTINCT SPECIES COMPRISING:

- 1. SECRETED COMPOUNDS- SAID CLAIMS CURRENTLY READ ON AN INFINITE NUMBER OF COMPOUNDS
- 2. ORGANISM (DONOR, HOST, MICRO- OR OTHERWISE)- SAID CLAIMS CURRENTLY READ ON AN INFINITE NUMBER OF ORGANISMS
- 3. ANTIBODIES- SAID CLAIMS CURRENTLY READ ON AN INFINITE NUMBER OF ANTIBODIES

THIS APPLICATION CONTAINS CLAIMS DIRECTED TO THE FOLLOWING PATENTABLY DISTINCT SPECIES OF THE CLAIMED INVENTION:

- A) ENZYMES, OTHER (NON-ENZYMATIC?) PROTEINS, PEPTIDES (CLAIM 2)
- B) AT LEAST ONE ADDITIONAL SCREENING STEP (CURRENTLY READS ON AN INFINITE NUMBER AND TYPE OF SCREENING STEPS) (CLAIM 3)

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- C) AN ENZYME (CLAIM 6)
- D) A FUNCTIONAL ASSAY (CLAIM 6)
- E) A MICROORGANISM (CLAIM 7)
- F) AN ASSAY FOR A SECRETED COMPOUND (CLAIM 8)
- G) A DESIRED FUNCTIONALITY (E.G., WASH PERFORMANCE, THERMAL STABILITY, SUBSTRATE SPECIFICITY, CATALYTIC TURNOVER, OXIDATION STABILITY, SENSITIVITY TO INHIBITORS, PH OPTIMUM, DETERGENT STABILITY, STABILITY AGAINST MICROBIAL INACTIVATION, TOXICOLOGY, DISTRIBUTION PROFILE IN THE HUMAN OR ANIMAL BODY, METABOLIZATION PRODUCTS, SIDE EFFECTS, RATE OF METABOLIZATION OR SECRETION, RECEPTOR BINDING CAPACITY, ANTIMICROBIAL CAPACITY) (CLAIM 9)
- H) A GENE LIBRARY (CLAIM 10)
- I) A COMPOUND ( CLAIM 12; CURRENTLY READS ON AN INFINITE NUMBER OF COMPOUNDS)
- J) PROTEINS AND PEPTIDES (CLAIM 13; CURRENTLY READS ON AN INFINITE NUMBER OF PROTEIC MOLECULES)
- K) AN ENZYME (CLAIM 14; CURRENTLY READS ON AN UNSEARCHABLE NUMBER OF ENZYMES)
- L) A SCREENED MICROORGANISM (E.G., A GENUS, E.G., BACILLUS) (CLAIM 18)
- M) A SCREENED MICROORGANISM (E.G., AN ULTIMATE SPECIES, E.G., BACILLUS AGARADHAERENS) (CLAIM 18)
- N) AN ENVIRONMENTAL SAMPLE (E.G., SOIL) (CLAIM 19)

THE SPECIES MENTIONED ABOVE HAVE DIFFERENT AND SEPARATELY BURDENSOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND HAVE DIVERGENT SUBJECT MATTER.

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APPLICANT IS REQUIRED UNDER 35 U.S.C. 121 TO ELECT A SINGLE DISCLOSED SPECIES FOR PROSECUTION ON THE MERITS TO WHICH THE CLAIMS SHALL BE RESTRICTED IF NO GENERIC CLAIM IS FINALLY HELD TO BE ALLOWABLE.

APPLICANT IS ADVISED THAT A REPLY TO THIS REQUIREMENT MUST INCLUDE AN IDENTIFICATION OF THE SPECIES THAT IS ELECTED CONSONANT WITH THIS REQUIREMENT, AND A LISTING OF ALL CLAIMS READABLE THEREON, INCLUDING ANY CLAIMS SUBSEQUENTLY ADDED. AN ARGUMENT THAT A CLAIM IS ALLOWABLE OR THAT ALL CLAIMS ARE GENERIC IS CONSIDERED NONRESPONSIVE UNLESS ACCOMPANIED BY AN ELECTION.

UPON THE ALLOWANCE OF A GENERIC CLAIM, APPLICANT WILL BE ENTITLED TO CONSIDERATION OF CLAIMS TO ADDITIONAL SPECIES WHICH ARE WRITTEN IN DEPENDENT FORM OR OTHERWISE INCLUDE ALL THE LIMITATIONS OF AN ALLOWED GENERIC CLAIM AS PROVIDED BY 37 CFR 1.141. IF CLAIMS ARE ADDED AFTER THE ELECTION, APPLICANT MUST INDICATE WHICH ARE READABLE UPON THE ELECTED SPECIES. MPEP § 809.02(A).

SHOULD APPLICANT TRAVERSE ON THE GROUND THAT THE SPECIES ARE NOT PATENTABLY DISTINCT, APPLICANT SHOULD SUBMIT EVIDENCE OR IDENTIFY SUCH EVIDENCE NOW OF RECORD SHOWING THE SPECIES TO BE OBVIOUS VARIANTS OR CLEARLY ADMIT ON THE RECORD THAT THIS IS THE CASE. IN EITHER INSTANCE, IF THE EXAMINER FINDS ONE OF THE INVENTIONS UNPATENTABLE OVER THE PRIOR ART, THE EVIDENCE OR ADMISSION MAY BE USED IN A REJECTION UNDER 35 U.S.C. 103(A) OF THE OTHER INVENTION.

APPLICANT IS REMINDED THAT UPON THE CANCELLATION OF CLAIMS TO A NON-ELECTED INVENTION, THE INVENTORSHIP MUST BE AMENDED IN COMPLIANCE WITH 37 CFR 1.48(B) IF ONE OR MORE OF THE CURRENTLY NAMED INVENTORS IS NO LONGER AN INVENTOR OF AT LEAST ONE CLAIM REMAINING IN THE APPLICATION. ANY AMENDMENT OF INVENTORSHIP MUST BE ACCOMPANIED BY A REQUEST UNDER 37 CFR 1.48(B) AND BY THE FEE REQUIRED UNDER 37 CFR 1.17(I).

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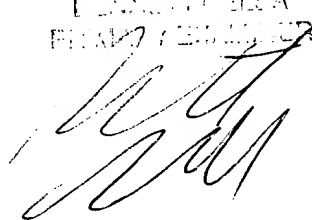
ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DEVON R BYRD WHOSE TELEPHONE NUMBER IS 703-305-0159. THE EXAMINER CAN NORMALLY BE REACHED ON MON-FRI 8A-4P.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, ANDREW WANG CAN BE REACHED ON 703-306-2317. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS (703) 872-9306.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE RECEPTIONIST WHOSE TELEPHONE NUMBER IS 703-308-1235.

DB  
SEPTEMBER 30, 2003

FORNITT CELSA  
RECEIVED

A handwritten signature in black ink, appearing to be 'J. Wang', is written over the 'RECEIVED' stamp.